



In re Patent Application  
of Inventor(s) LEE  
Appn. No. 08

Series  
Code ↑

Filed: February 27, 1996

Title: GDF-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT  
APPLICATION

Group Art Unit: 1818  
Examiner: M.P. Allen  
Atty. Dkt. 220253

Old M#  
(Our Deposit Account No. 03-3975)  
(Our Order No. 20263)

Client Ref  
4/97138  
220253  
C#

U.S. PRO  
11/17/97  
OIPM#

607,485  
Serial No. ↑

Hon. Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Sir:

Applicant hereby petitions to extend the life of this application to and through at least the above dates so as to copend with a continuing application. The requisite extension fee is enclosed.

1. The original due date in the subject application was September 17, 1997

2. Extension fee required

Large/Small Entity	Fee Code
(1 mo) \$110/\$55	115/215
(2 mos) \$400/\$200	116/216
(3 mos) \$950/\$475	117/217
(4 mos) \$1510/\$755	118/218
+ 200	
-	
\$200	

3. Enter any previous extension fee paid since last Action ..... subtract

4. CHECK ATTACHED FOR FEE OF

5.  "Small entity" verified statement filed:

herewith.

previously.

Please charge any missing or inadequate fee re this petition to our Deposit Account/Order Nos. shown in the heading hereof for which purpose a duplicate copy of this sheet is attached:

Cushman Darby & Cushman  
Intellectual Property Group of  
Pillsbury Madison & Sutro LLP

1100 New York Avenue, N.W.  
Ninth Floor, East Tower  
Washington, D.C. 20005-3918  
Tel: (202) 861-3000  
PNK/ms

By: Atty: Paul N. Kokulis Reg No. 16,773

Sig: Reu Fax: (202) 822-0944

Tel: (202) 861-3503

NOTE: This paper must be headed in the parent application of, and filed in duplicate and separately from, Rule 60, 62, continuation, division or CIP papers, with separate PTO receipt (CDC-103A).

12/10/1997 DRUTLER 0050043 000000000000  
01 F0-216



A/FWC

Page 1 of 4

PATENT  
APPLICATION

## IN THE UNITED STATES PATENT AND TRADEMARK

## OFFICE

## REQUEST FOR FILE WRAPPER CONTINUING APPLICATION UNDER 37 CFR 1.62

## (RULE 62)

## For Design or Utility Applications

BOX FWC

The Hon. Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Prior Application: 08/607,485

Group Art Unit: 1818

Examiner: M.P. Allen

Atty Dkt: 241801/

new M#/Client Ref.

(Our Deposit Account No. 03-3975

(Our Order No. 20263/241801

, a C# / new M#

series code ↑ ↑ serial no. Date: November 17, 1997

Sir:

This is a RULE 62 REQUEST for filing from  
prior copending parent Application No. 08/607,485

 divisional continuation (**Exr. NOTE:** any election in parent as to species/restriction requirement: is carried over with traverse ( is not carried over) continuation-in-part without new Declaration (Rule 62(d)) without fee continuation-in-part (with new Declaration attached hereto)

The parent was filed on February 27, 1996, entitled GDF-1,

by the following named inventor(s) who is/are  the same as,  less than all of (see Item 17),

more than (for CIP only), those named in that parent application:

(1) Inventor	Se-Jin	LEE	
Residence	Baltimore, Maryland	Maryland, USA	USA
Post Office Address (include Zip Code)	2509A Steele Road, Baltimore, Maryland 21209	State/Foreign Country	Country of Citizenship
(2) Inventor			
Residence			
Post Office Address (include Zip Code)		State/Foreign Country	Country of Citizenship
(3) Inventor			
Residence			
Post Office Address (include Zip Code)		State/Foreign Country	Country of Citizenship
(4) Inventor			
Residence			
Post Office Address (include Zip Code)		State/Foreign Country	Country of Citizenship
(5) Inventor			
Residence			
Post Office Address (include Zip Code)		State/Foreign Country	Country of Citizenship

**NOTE: FOR ADDITIONAL INVENTORS**, check box  and attach sheet (CDC-110A) with same information with  
same information for each inventor starting with inventor No. 6 and number new page 1A.

1. **Requirement of Rule 62:** Rule 62 filings are to be used only when the issue fee has not been paid (except as noted below) in the above-identified prior application nor that application abandoned or its proceedings terminated. This Rule 62 filing will be considered by the PTO as an express abandonment of that prior application except when this Rule 62 filing is pursuant to Rule 313(b)(5), i.e., when the issue has been paid in the prior application and a petition filed to abandon that application to permit an IDS to be considered in this Rule 62 application. (Note: 37 CFR 1.53 (Rule 53) may be used for continuations and divisions where the prior application is not to be abandoned.)

2.  The issue fee has been paid in the parent, but this Rule 62 Request follows a Rule 313(b)(5) petition, and per 1138 OG 40 waiver is respectively requested of that part of Rule 62 which prohibits use of the rules to file an FWC after payment of the issue fee.

3.  Priority is claimed under 35 U.S.C. 119/365 based on filing in \_\_\_\_\_ of: \_\_\_\_\_  
(country)

Application No. Filing Date Application No. Filing Date

- (1) \_\_\_\_\_
- (2) \_\_\_\_\_
- (3) \_\_\_\_\_

—  
—

Application No.

**Filing Date**

• 100 •

(4) \_\_\_\_\_  
(5) \_\_\_\_\_  
(6) \_\_\_\_\_

a.  \_\_\_\_\_ (No.) Certified copy/copies attached.

b.  Certified copy/copies previously filed on \_\_\_\_\_ in prior  
U.S. Application No. \_\_\_\_\_ / \_\_\_\_\_, filed on \_\_\_\_\_.  
series code  $\uparrow$   $\uparrow$  serial no.

c.  Certified copy/copies filed during International stage of PCT/ \_\_\_\_\_. / \_\_\_\_\_.  
d.  Priority is also claimed from PCT/ \_\_\_\_\_. filed \_\_\_\_\_. / \_\_\_\_\_.  
Priority date \_\_\_\_\_ / \_\_\_\_\_. / \_\_\_\_\_.  
Priority document number \_\_\_\_\_

4.  The prior application is assigned of record to Carnegie Institute of Washington by Assignment recorded January 16, 1991 Reel 5582 Frame 797.

5.  Attached is an assignment Cover Sheet.

Please return the recorded Assignment to the undersigned.

6.  The power of attorney in the prior application is to Paul N. Kokulis, Reg. No. 16,773  
CUSHMAN DARBY & CUSHMAN IP GROUP OF PILLSBURY MADISON & SUTRO LLP  
(Name, Reg. No.) ↑

7.  Recognize as associate attorney

(Name and Reg. No.; Address as in item 8 unless otherwise indicated) ↑

8. **Address all future communications to Cushman Darby & Cushman, Intellectual Property Group of Pillsbury Madison & Sutro LLP, Ninth Floor, East Tower 1100 New York Avenue, N.W., Washington, D.C. 20005-3918**

9.  Amend the specification by inserting before the first line (in place of any comparable insert previously requested in any prior application) the sentence: --This is a

continuation-in-part (CIP)  continuation  division  
of application No. 08/607,485, filed on February 27, 1996, which was  
series code        serial no.         
abandoned upon the filing hereof, which is a continuation of Serial No. 08/583,491, filed January 5, 1996,  
now abandoned, which is a continuation of Serial No. 08/316,456, filed October 3, 1994, now  
abandoned, which is a continuation of Serial No. 08/900,002, filed July 12, 1993, now abandoned, which  
is a continuation of Serial No. 07/614,452, filed November 16, 1990, now abandoned, which is a  
continuation-in-part of Serial No. 07/538,372, filed June 15, 1990, now abandoned.

10.  1 (No.) Verified Statement(s) establishing "small entity" status under Rules 9 and 27  
a.  filed in above prior application (and hence applicable hereto)  
b.  attached

11. **Requirement of Rule 62:** It is understood that secrecy under 35 U.S.C. 122 is hereby waived to the extent that if information or access is available to any one of the applications in the file wrapper of a 37 CFR 1.62 application, be it either this application or a prior application in the same file wrapper, the Patent and Trademark Office may provide similar information or access to all the other applications in the same file wrapper.

12. Petition to extend the life of the above prior application to at least the date hereof

NOTE: (One box)  is being concurrently filed in that prior application (Use From CDC-111).  
 (must be)  was previously filed in that prior application (Check length of prior extension).  
 (X'd)  is not necessary for copendency (Double check before X'ing this box).

13.  Please enter the amendment previously filed on \_\_\_\_\_  
 but unentered in the above prior application.

14.  Attached: sheet(s) per set of drawing of Fig(s) :  
 1 set informal;  formal of size:  A4  11"

15.  **PRELIMINARY AMENDMENT to be entered before fee calculation** (Do not make amendments here except cancellation of whole claims or multiple dependencies for purpose of reducing the filing fee per MPEP §§ 506 and 607; do not cancel all claims.):

16.  Attached is a Rule 103(a) Petition to suspend action

17. Petition is hereby made requesting deletion as inventor(s) of the following who is/are not inventor(s) of the invention being claimed in this Rule 62 application:

1. \_\_\_\_\_  
 3. \_\_\_\_\_

2. \_\_\_\_\_  
 4. \_\_\_\_\_

18.  This Rule 62 application is a continuation-in-part which discloses and claims additional matter and the amendments in attached Amendment are to be considered an integral part of the CIP ab initio.  
 a.  New Declaration is attached.  
 b.  This application is also filed under Rule 62(d) (without a Declaration) and hence filing fee is not enclosed.

**FILING FEE**

**THE FOLLOWING FILING FEE IS BASED ON THE CLAIMS  
 EXISTING IN THE PRIOR APPLICATION AS AMENDED AT 13 AND 15 ABOVE**

				<b>Large/Small Entity</b>		<b>Fee Code</b>
19. Basic Filing Fee .....		Design Application		\$330/\$165		106/26
20.		Not Design Application		\$790/\$395	+395	101/201
21. Total Effective Claims	7	minus 20 =	0	x \$22/\$11	+0	103/203
(Base this on claims as amended to effect CIP if this is a Rule 62(d) completion)						
22. Independent Claims	2	minus 3 =	0	x \$82/\$41	+0	102/202
23. If <u>any</u> <u>proper</u> multiple dependent claim (ignore improper) is present, (Leave this line blank if this is a reissue application)				\$270/\$135	+0	104/204
24.				<b>TOTAL FILING FEE =</b>	<b>\$395</b>	
25. If "assignment" box 5 is X'd, add recording fee.				\$40	+	581
26. If "petition" box 16 above is X'd, add petition fee.				\$130	+130	122
27.				<b>FEE ATTACHED =</b>	<b>\$525</b>	
(carry forward to line 36)						

28.  Preliminary Amendment attached (to be entered after assigning Appln. No.).  
 (Do NOT X box 28 or 29 for CIP Amendment. See box 18)

29.  The following PRELIMINARY AMENDMENT is to be entered after assigning Appln. No.:

30.  ATTACHED:  
 PRELIMINARY AMENDMENT and REQUEST FOR SUSPENSION OF ACTION

**ADDITIONAL FEE CALCULATION FOR  
 PRELIMINARY AMENDMENT  
PER BOXES 28/29**

Claims remaining after amendment	Highest number previously paid for	Present Extra	Additional Fee
---	---	------------------	-------------------

		<u>Large/Small Entity</u>	<u>File Code</u>
32.	Total Effective Claims <u>9</u>	minus ** <u>20</u> = * <u>0</u> x \$22/\$11 = <u>\$ 0</u>	(103/203)
33.	Independent Claims <u>2</u>	minus *** <u>3</u> = * <u>0</u> x \$82/\$41 = <u>+ 0</u>	(102/202)
34.	If amendment enters proper multiple dependent claim(s) into this application for the <u>first time</u> , add .....	\$270/\$135(per application) <u>+ 0</u>	(104/204)
35.		<b>ADDITIONAL FEE</b> <u>\$ 0</u>	
36.		<u>plus FEE</u> from item 27 on page 3 <u>+ 525</u>	
37.		<b><u>TOTAL FEE ATTACHED</u></b> <u>\$ 525</u>	

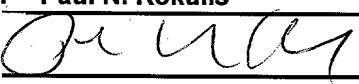
38. \*If the entry in the first space is less than an entry in the middle space, the "Present Extra" result is "0"

39. \*\*If the "Highest number previously paid for" (see item 21 above) is less than 20, write "20" in this space

40. If the "Highest number previously paid for" (see item 22 above) is less than 3, write "3" in this space

**CHARGE STATEMENT:** The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any missing or insufficient fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (missing or insufficient fee only) now or hereafter relative to this application and the resulting Official document under Rule 20, or credit any overpayment, to our Account/Order Nos. shown in the heading hereof for which purpose a duplicate copy of this sheet is attached. This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal form is filed.

**Cushman Darby & Cushman  
 Intellectual Property Group of  
 Pillsbury Madison & Sutro LLP**

**1100 New York Avenue, N.W.** By: Atty: Paul N. Kokulis Reg. No. 16,773  
**Ninth Floor East Tower**  
**Washington, D.C. 20005-3918** Sig:  Fax: (202) 822-0944  
 Tel: (202) 861-3000 Tel: (202) 861-3503  
 PNK/ms

**NOTE: No: 1:** File this Request in duplicate with 2 postcard receipts (CDC-103) & attachments  
**NOTE: No: 2:** Is extension in parent necessary for copendency? **DOUBLE CHECK** Item 12 above.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

**LEE**

FWC of Appln. No. 08/607,485

Group Art Unit: 1818

Filed: November 17, 1997

Examiner: M. Allen

FOR: GDF-1

\* \* \*

November 17, 1997

**REQUEST FOR SUSPENSION OF ACTION**

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Sir:

In accordance with the provisions of 37 C.F.R. 1.103(a),  
request by way of petition is hereby made to suspend action on  
the above-referenced application by the U.S. Patent and  
Trademark Office for a period of six months, up to and  
including May 17, 1998, based on the following showing of good  
and sufficient reasons.

A file wrapper continuing (FWC) application under 37  
C.F.R. 1.62 is being filed together with this petition.  
Therefore, no response by applicant to an Office Action is  
required.

12/10/1997 DBUTLER 00000042 08971338  
02 FCI:122 In the Office Action of May 17, 1997, the Examiner has  
maintained her rejection of the claims under 35 U.S.C. 112,  
first paragraph. The Examiner's position appears to be that  
the specification's disclosure of how the claimed invention is  
to be used is not credible in the absence of declaration

LEE - FWC of Appln. No. 08/607,485

evidence supporting those uses. Although this position is disputed, such evidence is currently being obtained in the interest of furthering prosecution in this application.

In view of time required to produce GDF-1, establish an assay which would support use of GDF-1 as disclosed in the specification, collect data from the assay, and prepare a declaration based on the data, applicant requests suspension of action so that the necessary data may be presented to the Examiner prior to a first Office Action on the merits. Like the recombinant production of GDF-1, assays which would establish the biological activity of GDF-1 are known in the art. Applicant submits that such declaration evidence will allow the Examiner to withdraw the enablement rejection and allow the pending claims.

Thus, it is the intent of the undersigned to place the present application in the best posture for further consideration by the Examiner.

The fee as required by 37 C.F.R. 1.17(i) is enclosed herewith. If this fee is missing or insufficient, the Office is hereby authorized to charge our Deposit Account No. 03-3975, Order No. 20263/241801 for the missing or insufficient amount, for which purpose a duplicate copy of this paper is attached.

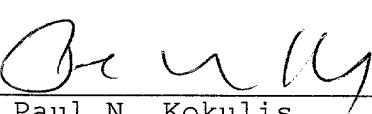
LEE - FWC of Appln. No. 08/607,485

Prompt consideration of this petition and a favorable response are earnestly requested. The Office is invited to contact the undersigned if further information is needed.

Respectfully submitted,

Cushman Darby & Cushman  
Intellectual Property Group of  
PILLSBURY MADISON & SUTRO, L.L.P.

By



Paul N. Kokulis  
Reg. No. 16,773  
Telephone: (202) 861-3503  
Facsimile: (202) 822-0944

PNK/GRT  
1100 New York Avenue, N.W.  
Ninth Floor, East Tower  
Washington, D.C. 20005-3918  
Phone: (202) 861-3503

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

**LEE**

FWC of Appln. No. 08/607,485

Group Art Unit: 1818

Filed: November 17, 1997

Examiner: M. Allen

FOR: GDF-1

\* \* \*

November 17, 1997

**PRELIMINARY AMENDMENT**

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Sir:

Entry and consideration of the following amendment and  
remarks prior to examination are respectfully requested.

**IN THE CLAIMS:**

Please add the following claims.

--22. The protein according to claim 4 wherein said  
protein has a molecular weight of 41K or 38K as shown in  
Figure 4.

23. The protein according to claim 9 wherein said  
protein has a molecular weight of 41K or 38K as shown in  
Figure 4.--

**REMARKS**

The Examiner's attention is directed to the accompanying petition submitted under 37 C.F.R. 1.103(a); the petition requests suspension of action in the present application. A decision on this petition is requested prior to examination and issuance of a first Office Action. Further, if the declaration to be submitted prior to May 17, 1998 has not reached the Examiner when this application is taken up for examination, she is invited to contact the undersigned.

Claims 4-10 and 22-23 are pending. New claims 22-23 are directed to GDF-1 protein lacking a signal peptide as shown by *in vitro* translation of full-length GDF-1 transcript in the presence of dog pancreas microsomes (Example 2).

The amendments to the claims find support throughout the original disclosure and, thus, do not introduce new matter. See, in particular, pages 20-22 of the specification.

Claims 4-10 were rejected under 35 U.S.C. 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention". Applicant traverses.

Contrary to the statement on pages 2-3 of the Office Action (Paper No. 4), applicant does not agree with the Examiner that uses of the claimed invention discussed in the

previous Office Action are not enabled. Applicant is not arguing that a person skilled in the art would have to "dream up" potential uses of the present invention. Instead, applicant submits that the Examiner has not explained in previous Office Actions why the objective truth contained in the disclosure is doubted by "evidence or reasoning which is inconsistent with the contested statement". M.P.E.P. 2164.01 and *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971). No such evidence or reasoning was given in the previous Office Actions, the Examiner merely stated her belief that "it could not be predicted which activity GDF-1 would have, if any" (page 2 of Paper No. 3). Thus, the Examiner's objection appears to be based on the lack of working examples in the specification. However, applicant submits that working examples are not required in order to comply with Section 112, first paragraph, (M.P.E.P. 2164.02) especially in view of the other examples provided in the specification.

Although applicant maintains that this is sufficient to overcome the Examiner's objection to the specification, a declaration is being prepared to further prosecution in the present application. As discussed in the petition, suspension is requested to allow applicant time to prepare a declaration containing evidence responsive to the pending enablement rejection. Such declaration evidence should be further considered as a response to the pending enablement rejection.

Finally, it is noted that the Hoben et al. reference supports the use of GDF-1 as a lineage marker because of its expression "primarily in the nervous system". Further, the cited abstract does not support the Examiner's allegation that "biological activity, and assays therefore, for GDF-1 had not been determined at the time of the invention" (page 5 of the Office Action, Paper No. 4). Instead the abstract describes further characterization of GDF-1 and studies showing that recombinant GDF-1 "stimulates the expression of the immediate early genes in neural cell lines". Thus, one would not conclude from the abstract that GDF-1 does not have a biological activity or that such activities as disclosed in the present application are incredible.

A favorable action on the merits is earnestly requested. If any further information is required, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Cushman Darby & Cushman  
Intellectual Property Group of  
PILLSBURY MADISON & SUTRO, L.L.P.

By



Paul N. Kokulis  
Reg. No. 16,773  
Telephone: (202) 861-3503  
Facsimile: (202) 822-0944

PNK/GRT  
1100 New York Avenue, N.W.  
Ninth Floor, East Tower  
Washington, D.C. 20005-3918  
Phone: (202) 861-3503

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

**LEE**

FWC of Appln. No. 08/607,485

Group Art Unit: 1818

Filed: November 17, 1997

Examiner: M. Allen

FOR: GDF-1

\* \* \*

November 17, 1997

**REQUEST FOR SUSPENSION OF ACTION**

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Sir:

In accordance with the provisions of 37 C.F.R. 1.103(a), request by way of petition is hereby made to suspend action on the above-referenced application by the U.S. Patent and Trademark Office for a period of six months, up to and including May 17, 1998, based on the following showing of good and sufficient reasons.

A file wrapper continuing (FWC) application under 37 C.F.R. 1.62 is being filed together with this petition. Therefore, no response by applicant to an Office Action is required.

In the Office Action of May 17, 1997, the Examiner has maintained her rejection of the claims under 35 U.S.C. 112, first paragraph. The Examiner's position appears to be that the specification's disclosure of how the claimed invention is to be used is not credible in the absence of declaration

evidence supporting those uses. Although this position is disputed, such evidence is currently being obtained in the interest of furthering prosecution in this application.

In view of time required to produce GDF-1, establish an assay which would support use of GDF-1 as disclosed in the specification, collect data from the assay, and prepare a declaration based on the data, applicant requests suspension of action so that the necessary data may be presented to the Examiner prior to a first Office Action on the merits. Like the recombinant production of GDF-1, assays which would establish the biological activity of GDF-1 are known in the art. Applicant submits that such declaration evidence will allow the Examiner to withdraw the enablement rejection and allow the pending claims.

Thus, it is the intent of the undersigned to place the present application in the best posture for further consideration by the Examiner.

The fee as required by 37 C.F.R. 1.17(i) is enclosed herewith. If this fee is missing or insufficient, the Office is hereby authorized to charge our Deposit Account No. 03-3975, Order No. 20263/241801 for the missing or insufficient amount, for which purpose a duplicate copy of this paper is attached.

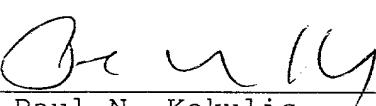
LEE - FWC of Appln. No. 08/607,485

Prompt consideration of this petition and a favorable response are earnestly requested. The Office is invited to contact the undersigned if further information is needed.

Respectfully submitted,

Cushman Darby & Cushman  
Intellectual Property Group of  
PILLSBURY MADISON & SUTRO, L.L.P.

By



Paul N. Kokulis  
Reg. No. 16,773  
Telephone: (202) 861-3503  
Facsimile: (202) 822-0944

PNK/GRT  
1100 New York Avenue, N.W.  
Ninth Floor, East Tower  
Washington, D.C. 20005-3918  
Phone: (202) 861-3503

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

**LEE**

FWC of Appln. No. 08/607,485

Group Art Unit: 1818

Filed: November 17, 1997

Examiner: M. Allen

FOR: GDF-1

\* \* \*

November 17, 1997

**PRELIMINARY AMENDMENT**

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Sir:

Entry and consideration of the following amendment and  
remarks prior to examination are respectfully requested.

**IN THE CLAIMS:**

Please add the following claims.

--22. The protein according to claim 4 wherein said  
protein has a molecular weight of 41K or 38K as shown in  
Figure 4.

23. The protein according to claim 9 wherein said  
protein has a molecular weight of 41K or 38K as shown in  
Figure 4.--

REMARKS

The Examiner's attention is directed to the accompanying petition submitted under 37 C.F.R. 1.103(a); the petition requests suspension of action in the present application. A decision on this petition is requested prior to examination and issuance of a first Office Action. Further, if the declaration to be submitted prior to May 17, 1998 has not reached the Examiner when this application is taken up for examination, she is invited to contact the undersigned.

Claims 4-10 and 22-23 are pending. New claims 22-23 are directed to GDF-1 protein lacking a signal peptide as shown by *in vitro* translation of full-length GDF-1 transcript in the presence of dog pancreas microsomes (Example 2).

The amendments to the claims find support throughout the original disclosure and, thus, do not introduce new matter. See, in particular, pages 20-22 of the specification.

Claims 4-10 were rejected under 35 U.S.C. 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention". Applicant traverses.

Contrary to the statement on pages 2-3 of the Office Action (Paper No. 4), applicant does not agree with the Examiner that uses of the claimed invention discussed in the

previous Office Action are not enabled. Applicant is not arguing that a person skilled in the art would have to "dream up" potential uses of the present invention. Instead, applicant submits that the Examiner has not explained in previous Office Actions why the objective truth contained in the disclosure is doubted by "evidence or reasoning which is inconsistent with the contested statement". M.P.E.P. 2164.01 and *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971). No such evidence or reasoning was given in the previous Office Actions, the Examiner merely stated her belief that "it could not be predicted which activity GDF-1 would have, if any" (page 2 of Paper No. 3). Thus, the Examiner's objection appears to be based on the lack of working examples in the specification. However, applicant submits that working examples are not required in order to comply with Section 112, first paragraph, (M.P.E.P. 2164.02) especially in view of the other examples provided in the specification.

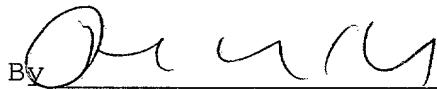
Although applicant maintains that this is sufficient to overcome the Examiner's objection to the specification, a declaration is being prepared to further prosecution in the present application. As discussed in the petition, suspension is requested to allow applicant time to prepare a declaration containing evidence responsive to the pending enablement rejection. Such declaration evidence should be further considered as a response to the pending enablement rejection.

Finally, it is noted that the Hoben et al. reference supports the use of GDF-1 as a lineage marker because of its expression "primarily in the nervous system". Further, the cited abstract does not support the Examiner's allegation that "biological activity, and assays therefore, for GDF-1 had not been determined at the time of the invention" (page 5 of the Office Action, Paper No. 4). Instead the abstract describes further characterization of GDF-1 and studies showing that recombinant GDF-1 "stimulates the expression of the immediate early genes in neural cell lines". Thus, one would not conclude from the abstract that GDF-1 does not have a biological activity or that such activities as disclosed in the present application are incredible.

A favorable action on the merits is earnestly requested. If any further information is required, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Cushman Darby & Cushman  
Intellectual Property Group of  
PILLSBURY MADISON & SUTRO, L.L.P.

By 

Paul N. Kokulis  
Reg. No. 16,773  
Telephone: (202) 861-3503  
Facsimile: (202) 822-0944

PNK/GRT  
1100 New York Avenue, N.W.  
Ninth Floor, East Tower  
Washington, D.C. 20005-3918  
Phone: (202) 861-3503